REMARKS

I. INTRODUCTION

The Office Action mailed on January 14, 2004 and the references cited therein have been carefully studied and, in view of the foregoing amendments and the following representations, reconsideration and allowance of this application are most respectfully requested.

Claims 1-10 are pending in the present application. Claims 6-10 have been withdrawn from consideration, claims 1-5 have been rejected under 35 U.S.C. § 102, and claim 5 has been rejected under 35 U.S.C. § 103. By the present amendment, claim 1 has been amended to correct a grammatical error by deleting the word "which," and claim 2 has been amended to correct a grammatical error by moving the word "the." In view of the following remarks, Applicant respectfully submits that the claims are in condition for allowance.

II. REJECTIONS UNDER § 102

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by: (1) U.S. Patent No. 5,643,201 to Peabody *et al.* ("Peabody *et al.*"); (2) U.S. Patent No. 5,542,919 to Simon *et al.* ("Simon *et al.*"); (3) U.S. Patent No. 3,620,215 to Tysk *et al.* ("Tysk *et al.*"); and (4) European Patent Application No. 0 149 001 ("EPA 0 149 001"). Claims 1-5 also stand rejected under 35 U.S.C.

§ 102(e) as being anticipated by U.S. Patent No. 6,409,699 to Ash ("Ash"). It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

To anticipate a claim, the reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Applicant respectfully submits that neither Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001, nor Ash discloses each and every element of independent claim 1.

Peabody *et al.* is directed to a continuous peritoneal dialysis apparatus. The method described in Peabody *et al.* "includes accumulating a sterilized dialysis fluid in a first reservoir, weighing the dialysis fluid in the first reservoir to determine a first prescribed volume of dialysis fluid, and filling a peritoneal cavity of a patient with the first prescribed volume of dialysis fluid from the first reservoir. Next, the method includes draining the dialysis fluid from the peritoneal cavity of the patient into a second reservoir, weighing the dialysis fluid in the second reservoir to determine a second prescribed volume of dialysis fluid, and terminating the draining of the dialysis fluid from the peritoneal cavity in response to weighing of the second prescribed volume of dialysis fluid in the second reservoir. The volume of fluid in the peritoneal cavity of the patient is monitored and the amount of dialysis fluid in the peritoneal cavity is adjusted to provide a desired

volume in the peritoneal cavity." Peabody *et al.*, col. 5, lines 21-36. However, Peabody *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Simon *et al.* is directed to a peritoneal dialysis device. The device disclosed in Simon *et al.* "has a balancing chamber that is divided into two halves by a movable, liquid-impermeable wall. The amount of liquid introduced into one half displaces the amount of fluid present in the other half in exact volumetric correspondence by displacement of the wall. As a result of this, the inlet and outlet volume can be determined with high accuracy, with an accuracy of one chamber volume (approx. 1% error), so that the ultrafiltered amount can also be determined accurately too." Simon *et al.*, col. 2, lines 47-55. However, Simon *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Tysk *et al.* is directed to an apparatus for peritoneal dialysis. Tysk *et al.* discloses "[a]n apparatus for peritoneal dialysis treatment of a patient operating automatically in accordance with a predetermined program comprising a plurality of successive dialysis cycles each consisting of a fill-phase during which fresh dialysis fluid is introduced into the peritoneal cavity of the patient, a dialysis-phase during which the dialysis fluid remains in the peritoneal cavity, and a drain-phase during

which the used dialysis fluid is withdrawn from the peritoneal cavity of the patient." Tysk *et al.*, abstract. However, Tysk *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

EPA 0 149 001 has been described in the background section of the present specification, as EPA 0 149 001 is directed to a peritoneal dialysis device. As described in the present specification, EPA 0 149 001 discloses a peritoneal dialysis device in which the ultrafiltration rate is controlled as a function of the intraperitoneal volume, so that "overfilling" of the patient is precluded, and wherein ultrafiltration control is based on measurement of dilution. The peritoneal dialysis device of EPA 0 149 001 comprises a closed circuit, in which dialyzing fluid circulates and to which a substance is added from outside whose secretion and resorption rate is negligible during the entire duration of treatment. The concentration of this exogenous substance in the peritoneal solution continuously decreases with increasing volume. During treatment, the concentration of this exogenous substance is measured and compared with the initial concentration at the start of treatment. When a difference between the measured concentration and the initial concentration is detected, the ultrafiltration means withdraws fluid from the peritoneal cavity until the initial concentration in the dialyzing fluid has been reestablished. However, EPA 0 149 001 does not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into

the peritoneal solution in the peritoneal cavity." In fact, as was described in the present specification, a drawback with the device disclosed in EPA 0 149 001 is that an exogenous substance must be added to the dialyzing fluid, and thus, incompatibilities cannot be ruled out. In addition, further secretion or resorption of the exogenous substance in EPA 0 149 001 may also result in defective control of the ultrafiltration rate.

Ash is directed to a continuous flow-through peritoneal dialysis (CFPD) method with control of intraperitoneal pressure. Ash discloses "devices and methods for treating patients suffering from renal insufficiency and/or hepatic insufficiency." Ash, col. 5, line 66 to col. 6, line1. The devices and methods disclosed in Ash "utilize in preferred embodiments the advantageous features of a dual lumen catheter, preferably a T-fluted dual lumen catheter, combined with a substantially constant rate of dialysate inflow and a pressure-dependent outflow controller ...." Ash, col. 6, lines 8-12. According to Ash, the devices and methods disclosed therein "provide[] in certain aspects advantageous systems for passing fluid through a patient's peritoneal cavity at a relatively high flow rate, while maintaining in the peritoneal cavity an optimal dialysate pressure, to thereby alter the contents of the patient's blood by diffusion of molecules through the peritoneal membrane." Ash, col. 6, lines 14-19. However, Ash does not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

In contrast to the teachings of Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001, and Ash, the method of the present invention, as currently recited in independent claim 1, includes "measuring the concentration of an *endogenous* substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity; and determining the intraperitoneal volume from the variation in the concentration over time" (emphasis added). As described in the specification, the method of the present invention is advantageous "in that exogenous substances need not be added. Therefore, determination of the intraperitoneal volume is less cumbersome and less costly. In addition, incompatibilities can be ruled out." Specification, page 3, lines 9-11.

Thus, Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001, and Ash do not disclose each and every element of the claimed invention as recited in independent claim 1. Thus, it is respectfully submitted that the rejections of independent claim 1, and dependent claims 2-5 therefrom, under 35 U.S.C. § 102 as being anticipated by Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001 or Ash have been overcome and should therefore be withdrawn.

III. REJECTIONS UNDER § 103

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001 in view of U.S. Patent No. 4,976,683 to Gauthier *et al.* ("Gauthier *et al.*"). Applicant

respectfully submits that this rejection should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

As discussed above, Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001 disclose various peritoneal dialysis devices. However, Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001, alone or in combination, do not teach nor suggest a method which includes "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal

solution in the peritoneal cavity; and determining the intraperitoneal volume from the variation in the concentration over time," as is currently recited in independent claim 1. Dependent claim 5 depends from independent claim 1, and thus includes this claim limitation as well. Thus, Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001 do not teach nor suggest the method of the invention as recited in dependent claim 5.

Gauthier *et al.* do not cure the shortcomings of Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001. Gauthier *et al.* is directed to a peritoneal dialysis method. According to the method disclosed in Gauthier *et al.*, "a fluid communication through the peritoneal membrane into the peritoneal cavity of a patient in need of peritoneal dialysis treatment is established," and "[a]n initial volume of an aqueous peritoneal dialysis composition containing an osmotic agent is instilled into the peritoneal cavity through the fluid communication." Gauthier *et al.*, abstract. Gauthier *et al.* also discloses that "[a] further amount of dissolved osmotic agent is released into the instilled dialysis composition to form a modified dialysis composition. That further osmotic agent is released in an amount sufficient to maintain a substantially constant osmolarity gradient between the modified dialysis composition and the body fluids such that the water and solute flux continues to enter into the modified dialysis composition during the predetermined dialysis time period. The modified dialysis composition is substantially removed from the peritoneal cavity at the end of the treatment time period." Gauthier *et al.*, abstract.

However, Gauthier *et al.* do not teach nor suggest a method which includes "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity; and determining the intraperitoneal volume from the variation in the concentration over time," as currently recited in dependent claim 5.

For at least the preceding reasons, Applicant respectfully submits that the rejection of pending claim 5 under 35 U.S.C. § 103(a) as obvious over Peabody *et al.*, Simon *et al.*, Tysk *et al.* and EPA 0 149 001 in view of Gauthier *et al.* has been overcome and should therefore be withdrawn.

IV. CONCLUSION

In light of the foregoing, Applicant respectfully submits that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,
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Dated: May 5, 2004

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